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(54) A REMOVAL AND AERATING CANNULA

(71) We, B. BRAUN MELSUNGEN AKTIENGESELLSCHAFT, a body corporate organised under the Laws of Germany, of 3508 Melsunge, Germany, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The invention relates to an apparatus for the removal of sterile injection fluids from storage containers provided with perforatable elastic and self-closing seal arrangements, comprising a removal and aeration cannula with means for aerating the said storage container with sterile air.

The cannula of the invention is formed by a hollow trocar, a self-closing valve and an air or bacteria filter preventing the passage of fluid.

Pharmaceutical preparations used for injections in the medical sphere are packed as individual doses in small volume glass ampullae and, when in use, after opening the ampulla, are removed with injection cannulae by means of a syringe and injected into the patient. Since the injection medium is only used for a single injection in these cases, the danger of bacterial contamination hardly ever arises during regular behaviour, as has been generally confirmed by practice and is therefore recognised as state of the art.

In addition to the containers and ampullae containing only a single dose of the injection medium, commercial forms of these preparations having a larger volume are however being offered to a great extent and a plurality of doses used per injection are accordingly produced. Injectable local anaesthetics containing for example, 50 to 100 ml of solution are marketed in this commercial form.

Such containers are usually sealed with a stopper composed of a quality of rubber suitable for repeated puncturing and successive doses may normally be removed *via* a cannula by means of a syringe. If the cannula used for removing the injection solution is also used for injecting the drug removed and thus withdrawn from the rubber stopper acting as an air-tight seal, then a quantity of air corresponding to the volume of liquid removed cannot flow into the container with the result that a vacuum is gradually formed which makes it more and more difficult to remove the fluid. In order to compensate for the reduced pressure being formed, it is necessary to supply a corresponding volume of bacteria-free air.

Another method for removal which is not in fact defendable for hygienic reasons makes use of a cannula which remains stuck permanently in the respective container seal, through which cannula the required quantity may be removed from the container using the syringe, the syringe removed from this removal cannula and injection carried out using a puncturing cannula. Air flows through the remaining cannula into the container still containing more injection solution to compensate the pressure, whereby the air is free of germs only if it has previously passed through a suitable bacteria filter. Such filters are not provided in the conventional cannulae so that there is always the latent risk of bacterial contamination of the content of the container and the associated risk of harm to the patient.

The subject of this application relates to a removal cannula suitable for removing injectable drugs which allows the quantity of fluid required for a single injection to be removed from a conventional container containing a plurality of individual does using a syringe and allows a volume of air corresponding to the volume of fluid removed to be supplied filtered free of bacteria, as part of the total removal procedure.

According to the invention there is provided an apparatus for the removal of sterile injection fluids from storage containers provided with perforatable elastic and self-closing seal arrangements comprising a removal and aeration cannula

with means for aerating the said storage containers with sterile air, wherein:

a) the cannula has a trocar whose outer diameter widens to a greater diameter at an insertion length from the said point for establishing and limiting the depth of penetration of the trocar into the said storage container;

b) a rubber insert with at least one slit and secured by a support ring in a widened part of the cannula of the trocar, in the internal passage of which a conical part of a syringe is insertable;

c) the rubber insert is fixed in the widened part of the trocar by means of an encircling rim in such a way that the rubber insert cannot be pushed forwards when the conical part of the syringe is introduced;

d) the outside of the rubber insert is arranged on the inside of the widened part of the cannula of the trocar as to be tight to air and fluid;

e) the widened part of the cannula of the trocar is connected *via* a passage to the interior of a housing in order to supply the filtered air passing through a filter;

f) a mounting with passages fixes the filter in position;

g) the ends of the slit rubber inserts are so spread by the insertion of the syringe cone that the contents of the container are taken up directly into the syringe.

In order to prevent wastage of injection medium, the length of the trocar should preferably not be substantially longer than the depth of the sealing arrangement, since it would not be possible to remove the contents completely from the inverted container with a longer trocar. In a widened section at the end of the cannula opposite the said point is provided an insert, shaped from a resilient rubber material, in whose internal central recess may be introduced the cone of a syringe used for removing fluid. The recess is dimensioned such that the syringe is held securely by the pressure of the said insert. The external diameter of the insert is smaller than the said widened cannula section provided for it so that it is pressed outwards when the syringe cone is introduced and laterally applied perforation may thus be sealed tight to fluids. A water and fluid-repellant bacteria filter is placed on the external side of this perforation in the path of the air passage to free the air flowing into the container of micro-organisms. Both the bacteria filter and the rubber insert may be fixed in their respective positions by annular mountings.

The hydrophobic filter acting as an air filter may be a deep-bed filter or a membrane filter composed of fibres having defined pore diameters (pore width from 20 to 0.5 μm preferably from 5 to 0.5 μm). The housing for the functional elements and the trocar may be produced in one part. The trocar should preferably widen to a greater diameter at a distance from the said point for establishing and limiting the depth of penetration.

With reference to the accompanying drawings:

Figure 1 shows the arrangement of container, removal cannula and syringe during removal of the injection medium from the container.

Figure 1 shows a longitudinal section through the container 2 holding the injection medium 1 in an inverted position corresponding to the usual removal position. The trocar of the removal and aeration cannula 5 is introduced into the container stopper 3 up to a trocar section of large diameter 6 which which acts as a stop. The contents of the container 1 may be removed through the passage 7 through the trocar as the removal procedure continues. The rubber insert 9 in whose internal passage 10 is shown the conical part 11 of a syringe 12, is placed in the widened part 8 of the trocar 4.

The insert 9 is fixed in the widening 8 of the trocar by an encircling rim 13 so that when the conical pat 11 is introduced, it cannot be pushed forwards and thus possibly cause the beginning 14 of the trocar passage 7 to be displaced. The Figure shows that the outside of the insert 9 is connected to the inside of the widened part 8 of the trocar 4 so as to be tight to air and fluids. the insert 9 is also secured by a support ring 15. The widened part 8 of the cannula of the trocar 4 is connected to the interior 17 of the housing 18 by a passage 16 and serves to supply the filtered air which has passed through the filter 19. A mounting 20 with the passages 21 fixed the filter 19 in its position. The ends 23 of the slit rubber insert 9 are spread so far by the cone 11 of the syringe 12 that the contents 1 of the container may be taken up directly into the syringe.

Figure 2 shows the same elements as Figure 1 but the arrangement thereof corresponds to the aeration state in which a quantity of air corresponding to the volume of fluid removed passes through the filter 19, the passage 16 and the interior 22, and through the cannula passage 7 into the container 2. The rubber insert 9 has assumed its original shape and the ends have come together so that fluid cannot penetrate to the internal passage 10 and flow outwards.

WHAT WE CLAIM IS:—

1. An apparatus for the removal of sterile injection fluids from storage containers provided with perforatable elastic and self-closing seal arrangements comprising a

removal and aeration cannula with means for aerating the said storage containers with sterile air, wherein:

a) the cannula has a trocar whose outer diameter widens to a greater diameter at an insertion length from the said point for establishing and limiting the depth of penetration of the trocar into the said storage container;

b) a rubber insert with at least one slit and secured by a support ring in a widened part of the cannula of the trocar, in the internal passage of which a conical part of a syringe is insertable;

c) the rubber insert is fixed in the widened part of the trocar by means of an encircling rim in such a way that the rubber insert cannot be pushed forwards when the conical part of the syringe is introduced;

d) the outside of the rubber insert is arranged on the inside of the widened part of the cannula of the trocar so as to be tight to air and fluid;

e) the widened part of the cannula of the trocar is connected *via* a passage to the interior of a housing in order to supply the filtered air passing through a filter;

f) a mounting with passages fixes the filter in position;

g) the ends of the slit rubber insert are so spread by the insertion of the syringe cone that the contents of the container are taken up directly into the syringe.

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Fig. 1

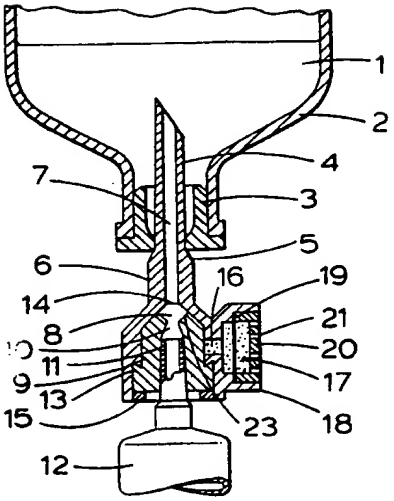

Fig. 2